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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,866	06/04/2001	Mark K. Hechinger	1007-103.US	4668

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EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 02/25/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,866

Applicant(s)

HECHINGER, MARK K.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-19 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claims 1-19 and group II, claims 25-26, in Paper No. 3 is acknowledged. The traversal is on the ground(s) that claims 25 and 26 are product claims based on the method of claim 1 and are entitled to inclusion in this election. This is not found persuasive because claim 25 directs to a no wash kit, and with a limitation of an "indicator antibody", which is not required by the claims of group I. Nevertheless, claim 26, an assay directs to the testing for the presence of a target substance using claim 1 method, can be considered into group I. Therefore, the examiner would regroup claim 26 into group I but remain claim 25 in group II as a patentably distinct and unrelated invention on the reasons as set forth above. Claims 20-25 are withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-19 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 8, "to an effective amount," is vague and indefinite. It is unclear as to what "effective" amount applicant refers to.

With respect to claim 1, line 6, "including washing the beads in the buffer," is vague and confusing. It is unclear and inconsistent to the preamble of the instant claim because the purported purpose of the recited method focuses on "no wash" bead assay whereas there includes a washing step in the recited method.

With respect to claim 1, line 11, “adding buffer,” is vague and indefinite. It is unclear whether this “buffer” is the first reagent buffer. Applicant needs to clearly specify.

With respect to claim 8, line 2, “selected from one or more of the *group* consisting of ,” is vague and confusing. Applicant needs to change the wording “group” to “groups” for clarity.

With respect to claim 12, “RNP/SM, SM, SS-A, SS-B, SCL-70 and dsDNA” is vague and indefinite. Applicant needs to clearly specify each of the recited substance.

With respect to claim 13, it shared the same problem as to the incorrect wording “group.” Furthermore, “one *of* more of the group” should be changed to “one *or* more of the groups”.

With respect to claim 13, “wherein the *antigens* are selected from one of more of the group consisting ofviral *antibodies*,.. bacterial *antibodies*,” is vague and confusing. It is well-known that antigen and antibodies are structural and functional different molecules. Antigen and antibody cannot be used interchangeably. Appropriate correction is needed.

With respect to claim 14, “the surfactancy of the beads is reduced to no more than 5% in order to enhance the ability,” is vague and confusing. It is unclear what applicant refers to the “5%”. Does applicant mean no more than 5% of coefficient of variation of the bead size as recited in the claim 1, or something particular other than such limitation. Appropriate specification is needed.

With respect to claim 26, it lacks the active steps as to show how one of ordinary skill in the art to conduct the assay of determining the presence of a target substance pursuant to purpose set forth in the preamble.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 5-11, 13-19 and 26 are rejected under 35 U.S.C. 102 (b) as anticipated by Hansen Peter. (USP 5286452)

Hansen teaches preparing immunoassay beads in a physiological buffer, i.e. HEPES. (Col. 13, line 54-55) Hansen also teaches selecting size of beads around coefficient of variation of diameter of particles ranged from 0.1- 4.0% to reduce surfactancy of the beads. (Col. 13, line 55-58) In addition, Hansen teaches that both Ag or Ab proteins could be coated on the beads for detection purpose. (Col. 2, line 24-26) Hansen teaches incubate the bead-antibody mixture with the buffer. (Col. 13, line 52-59) Hansen teaches using protein to block the non-specific binding sites on the beads, i.e. 0.1% or 0.5 BSA (Col. 13, line 67; Col. 14, line 48) Furthermore, Hansen teaches the sizes of the particles ranging from 0.02 to 12 μ m and using multiple-size beads for simultaneous assay. (Col. 12, line 25-40; Example 4) Hansen teaches detecting cellular antigens in human serum such as thyroid stimulating hormone (TSH). (Col. 14, line 35-40) Hansen also teaches prewashing bead buffer, centrifuging, vortexing and resuspension of the coated beads. (See Example 1, 2)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2, 3, 4 are rejected under 35 U.S.C. 103 (a) as unpatentable over Hensen in view of Fulwyler et al. (Method in Cell Biology, Vol. 33, Ch. 15 (1990) Page 613-629)

Hensen's reference has been discussed but Hansen does not explicitly teach using carbonate buffer for the coating process. Fulwyler et al. teach coating microparticles in flow cytometers for detection of analyte of interest. Fulwyler et al. teach that the coating process is dependent on the pH and the ionic strength of the buffer. (page 617, First paragraph) Fulwyler et al. teach using sodium bicarbonate buffer (pH = 9.5) for better noncovalent protein attachment of the microparticles. (See VI Appendix: Solutions and Suppliers) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of Hansen with the agent of carbonate buffer as taught by Fulwyler et al., for better adsorption of the antigens on the microparticles in the flow cytometer assay.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen in view of Lim et al. (Chemical Sensor (1998) 14: 77-80)(*English Abstract*)

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Hansen's reference has been discussed but fails specifically teaching using specific antigens, such as rheumatic diseases proteins, such as dsDNA, SS-B, SS-A or Scl-70. Lim et al. teach using automated flow immunoassay as a simple, rapid, and convenient method, to detect rheumatic related antibody dsDNA. (See abstract) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the assay method of Hansen to detect rheumatic disease proteins as taught by Lim et al. since using flow cytometer to detect cellular antigen or antibody is a routine clinical practice in the art for a simple, convenient and rapid analysis.

Conclusion

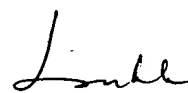
8. No claim is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
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LONG V. LE
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02/24/03

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February 23, 2003